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PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: DANIEL ALTMAN
KNOBBE MARTENS OLSON & BEAR, LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

	Date of mailing *(day/month/year)* 03 SEP 2008
Applicant's or agent's file reference FOUNDRY001VP	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US2008/060935	International filing date *(day/month/year)* 18 April 2008
Applicant THE FOUNDRY, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 14 35

   For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90*bis*.1 and 90*bis*.3, respectively, before the completion of the technical preparations for international publication.

   The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

   In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

   See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver Telephone No. 571-272-7774

Form PCT/ISA/220 (January 2004) *(See notes on accompanying sheet)*

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference FOUNDRY001VP	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US2008/060935	International filing date *(day/month/year)* 18 April 2008	(Earliest) Priority Date *(day/month/year)* 19 April 2007
Applicant THE FOUNDRY, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language**, the international search was carried out on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into _____ , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

   b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II)

3. ☐ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

   ☒ the text is approved as submitted by the applicant

   ☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

   ☒ the text is approved as submitted by the applicant

   ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

   a. the figure of the **drawings** to be published with the abstract is Figure No. 4

   ☐ as suggested by the applicant

   ☒ as selected by this Authority, because the applicant failed to suggest a figure

   ☐ as selected by this Authority, because this figure better characterizes the invention

   b. ☐ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/060935

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61N 1/38 (2008.04)
USPC - 607/1
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61N 1/38 (2008.04)
USPC - 607/1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
MicroPatent, DialogPro, Google Patents

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ---- Y	US 2006/0111744 A1 (MAKIN et al) 25 May 2006 (25.05.2006) entire document	1, 3, 4, 14, 15, 18, 21, 22, 25-30 ---------- 2, 5-13, 16, 17, 19, 20, 23, 24, 31-50
Y	US 2007/0060989 A1 (DEEM et al) 15 March 2007 (15.03.2007) entire document	2, 5, 13, 16, 17, 23, 24, 31-50
Y	US 2003/0130575 A1 (DESAI) 10 July 2003 (10.07.2003) entire document	6-13, 19, 20

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 August 2008	03 SEP 2008
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2005)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: DANIEL ALTMAN
KNOBBE MARTENS OLSON & BEAR, LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	03 SEP 2008
Applicant's or agent's file reference FOUNDRY001VP	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2008/060935	18 April 2008	19 April 2007

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61N 1/38 (2008.04)
USPC - 607/1

Applicant
THE FOUNDRY, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	24 August 2008	Blaine Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (April 2007)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2008/060935

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2008/060935

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	2, 5-13, 16-17, 19-20, 23-24, 31-50	YES
	Claims	1, 3-4, 14-15, 18, 21-22, 25-30	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-50	NO
Industrial applicability (IA)	Claims	1-50	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1, 3-4, 14-15, 18, 21-22 and 25-30, lack novelty under PCT Article 33(2) as being clearly anticipated by Makin et al.

Regarding claim 1, Makin et al. discloses an apparatus for treating a sweat gland of a patient (ultrasound transducer probe and control system are configured to deliver ultrasound energy to a targeted/specified depth and zone where the sweat gland population is to be treated, para. [0022]), comprising an energy generator (control system 202 and display 208, fig. 2B, comprise a system for power delivery, para. [0024]), an energy delivery device configured for placement proximate a skin tissue of the patient (probe 204, fig. 2B), wherein the energy delivery device is coupled to the energy generator (probe 204 coupled to control system 202, fig. 2B), and wherein the energy delivery device is configured to deliver energy to a target tissue within the skin tissue sufficient to at least partially destroy or disable at least one sweat gland within the target tissue (treatment resulting from ultrasound energy delivery in the region of sweat glands can be used to achieve selective ablation of regions of sub-epidermal region, para. [0029] and para [0030] wherein sweat glands are ablated).

Regarding claim 3, Makin et al. discloses wherein the energy delivery device comprises at least one energy delivery element selected from the group consisting of electrodes, antennas, ultrasound transducers, lasers, light emitting diodes, light bulbs, cryogenic probes, and combinations thereof (ultrasound transducer probe configured to deliver ultrasound energy to a targeted/specified depth and zone including the sweat gland, para. [0022]).

Regarding claim 4, Makin et al. discloses a cooling element configured for placement proximate a non-target tissue of the patient (cooling/coupling control system 306, fig. 3A).

Regarding claim 14, Makin et al. discloses a method of treating a patient, comprising identifying a patient having a condition of excessive sweating (eccrine sweat glands present deep in the dermis in the palms, soles and armpits; excessive activity of these glands results in copious amounts of abnormal sweating, para. [0003]), wherein the patient desires that sweating be reduced on at least a portion of the patient's body (reduction of sweating from under the armpits and other regions is a particularly desirable effect within the modern society, para. [0003]), positioning an energy delivery device proximate to a skin tissue of the patient (probe 204, fig. 2B), and delivering energy to a sweat gland of the patient sufficient to halt the secretion of sweat by at least partially disabling or destroying the sweat gland (treatment resulting from ultrasound energy delivery in the region of sweat glands used to achieve selective ablation of regions of sub-epidermal region, para. [0029]).

Regarding claim 15, Makin et al. discloses wherein positioning an energy delivery device further comprises positioning proximate to the skin tissue of the patient an energy delivery element selected from the group consisting of an electrode, antenna, ultrasound transducer, laser, light emitting diode, light bulb cryogenic probe and combinations thereof (ultrasound transducer probe configured to deliver ultrasound energy to a targeted/specified depth and zone including the sweat gland, para. [0022]).

Regarding claim 18, Makin et al. discloses wherein delivering energy to a sweat gland of the patient further comprises delivering energy to the sweat gland selected from the group consisting of electromagnetic, x-ray, radiofrequency, microwave, ultrasound, near infrared, infrared, intense pulsed light, visible light and laser and combinations thereof (ultrasound transducer probe configured to deliver ultrasound energy to a targeted/specified depth and zone including the sweat gland, para. [0022]).

Regarding claim 21, Makin et al. discloses providing protective cooling to the skin tissue (cooling/coupling control systems removes heat from probe to provide a controlled temperature at the superficial tissue interface and deeper into tissue, para. [0039]).

Regarding claim 22, Makin et al. discloses wherein providing protective cooling to the skin tissue further comprises positioning a cooling element proximate the skin tissue (cooling/coupling control systems removes heat from probe to provide a controlled temperature at the superficial tissue interface and deeper into tissue, para. [0039]).

Regarding claim 25, Makin et al. discloses visualizing the sweat gland using medical diagnostic imaging (ultrasound imaging used to define the position of a sweat gland, para. [0027]).

Regarding claim 26, Makin et al. discloses monitoring a diagnostic parameter of the skin tissue (monitoring the temperature profile or other tissue parameters of the region of interest, para. [0031]).

(Continued in Next Supplemental Box)

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box V

Regarding claim 27, Makin et al. discloses where the diagnostic parameter is selected from the group consisting of impedance, temperature, reflected light and reflected power (monitoring the temperature profile or other tissue parameters of the region of interest, para. [0031]).

Regarding claim 28, Makin et al. discloses wherein delivering energy to a sweat gland of the patient further comprises modulating energy delivery in response to a monitored diagnostic parameter (adjust the energy levels of the ultrasound therapy transducer of probe in response to monitoring the temperature profile, para. [0031]).

Regarding claim 29, Makin et al. discloses quantifying the reduction of sweating achieved in the patient or the treated portion of the patient's body (system software and firmware controls all initialization, timing, level setting, monitoring, safety monitoring, and all other system functions required to accomplish user-defined treatment objectives, para. [0040], reduction of sweating from under the armpits and other regions is a particularly desirable effect within the modem society, para. [0003]).

Regarding claim 30, Makin et al. discloses wherein at least a portion of the patient's body further comprises at least a portion of the patient's axillae (apparatus configured to treat sweat glands that require treatment in particular anatomical sites, such as, the axillary region, para. [0025]).

Claims 2, 5, 16-17, 23-24 and 31-50 lack an inventive step under PCT Article 33(3) as being obvious over Makin et al. in view of Deem et al.

Regarding claim 2, Makin et al. disclose the invention as disclosed in claim 1, but Makin et al does not disclose wherein the energy delivery device is configured for insertion into the target tissue. Deem et al. however, teaches an apparatus for treating skin of a patient (apparatus for targeting and disrupting subcutaneous structures, para. [0057]), wherein the energy delivery device is configured for insertion into the target tissue (ultrasound catheter having a handpiece 122 and a treatment shaft 124, is employed to disrupt subcutaneous structures, figs. 17A-17B). It would have been obvious to one skilled in the art at the time of the invention to modify the apparatus taught by Makin et al. to include the insertion device as taught by Deem et al. for the purpose of applying treatment energy to subcutaneous structures in the body needing treatment.

Regarding claim 5, Makin et al disclose the invention as disclosed in claim 1, but Makin et al. does not disclose a suction device configured for placement proximate the skin tissue of the patient. Deem et al. however, teaches an apparatus for treating a gland of a patient (apparatus for targeting and disrupting subcutaneous structures, para. [0057]), including a suction device configured for placement proximate the skin tissue of the patient (medical suction connected with the annular region 36 to pull the targeted region 100 and the device 30 against each other, para [0070]; fig. 1 and 2). It would have been obvious to one skilled in the art at the time of the invention to modify the apparatus taught by Makin et al. to include the suction device as taught by Deem et al. for the purpose of maintaining contact with the skin.

Regarding claim 16, Makin et al. disclose the invention as disclosed in claim 14, but Makin et al. does not disclose wherein positioning an energy delivery device further comprises inserting the energy delivery device within the skin tissue. Deem et al. however, teaches a method of treating a patient including positioning an energy device (treatment element 34 applied to the skin surface 102, fig. 2), wherein positioning an energy delivery device further comprises inserting the energy delivery device within the skin tissue (ultrasound catheter having a handpiece 122 and a treatment shaft 124, is employed to disrupt subcutaneous structures, figs. 17A-17B). It would have been obvious to one skilled in the art at the time of the invention to modify the method taught by Makin et al. to include inserting the energy delivery device within the skin tissue as taught by Deem et al. for the purpose of applying treatment energy to the treatment site.

Regarding claim 17, the modified Makin et al disclose the invention as disclosed in claim 16, but Makin et al. does not disclose wherein inserting the energy delivery device within the skin tissue further comprises inserting the energy delivery device into the skin tissue to a depth ranging from about 1 mm to about 8 mm beneath the surface of the skin. Deem et al. however, teaches a method of treating a patient including positioning an energy device (treatment element 34 applied to the skin surface 102, fig. 2), wherein inserting the energy delivery device within the skin tissue further comprises inserting the energy delivery device into the skin tissue to a depth ranging from about 1 mm to about 8 mm beneath the surface of the skin (microneedles extend into the skin a distance from 0.5 mm to 20 mm, depending on the target tissue to be treated, para. [0078]). It would have been obvious to one skilled in the art at the time of the invention to modify the method taught by Makin et al. to include the insertion depth as taught by Deem et al, for the purpose of applying treatment energy to the designated treatment site.

Regarding claim 23, Makin et al disclose the invention as disclosed in claim 14, but Makin et al does not disclose administering to the patient a medication selected from the group consisting of anesthetics, steroids, and antibiotics. Deem et al. however, teaches a method of treating a patient (methods and apparatus for achieving disruption of subcutaneous structures, para. [0061]), including administering to the patient a medication selected from the group consisting of anesthetics, steroids, and antibiotics (treatment enhancing agents may include, anesthetics such as lidocaine, vasoconstrictive agents such as epinephrine, hypotonic saline, potassium, agitated saline, microbubbles, adipocytes, fat, autologous tissues, and hydroxyappetite, para. [0068]). It would have been obvious to one skilled in the art at the time of the invention to modify the method taught by Makin et al. to include medication as taught by Deem et al. for the purpose of improving the comfort level of the patient.

(Continued in Next Supplemental Box)

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Previous Supplemental Page

Regarding claim 24, the modified Makin et al. disclose the invention as disclosed in claim 23, but Makin et al. does not disclose wherein administering medication to the patient further comprises administering the medication orally, topically or via injection. Deem et al. however, teaches a method of treating a patient (methods and apparatus for achieving disruption of subcutaneous structures, para. [0061]), wherein administering medication to the patient further comprises administering the medication orally, topically or via injection (energy delivery system having a central treatment element 34 used in conjunction with a subcutaneous injection of a treatment enhancing agent 54, fig. 6). It would have been obvious to one skilled in the art at the time of the invention to modify the method taught by Makin et al. to include the administration as taught by Deem et al. for the purpose of improving the comfort level of the patient.

Regarding claim 31, Makin et al. disclose the invention as disclosed in claim 14, but Makin et al. does not disclose elevating the skin tissue away from the underlying tissue prior to delivering energy to the sweat gland. Deem et al however, teaches a method of treating a patient by delivering energy to the skin tissue (methods and apparatus for achieving disruption of subcutaneous structures, para. [0061]), including elevating the skin tissue away from the underlying tissue prior to delivering energy to the sweat gland (skin 102 is sucked up towards needles 62 that are deployed out of the handpiece 268, fig. 7B). It would have been obvious to one skilled in the art at the time of the invention to modify the method taught by Makin et al. to include elevating the skin tissue as taught by Deem et al. for the purpose of bringing the skin into contact with the energy delivery device.

Regarding claim 32, the modified Makin et al disclose the invention as disclosed in claim 16, but Makin et al does not disclose wherein inserting the energy delivery device within the skin tissue further comprises inserting in the skin tissue an interstitial device selected from the group consisting of needles, stylets, catheters, probes and microneedles. Deem et al. however, teaches a method of treating a patient by delivering energy to the target tissue by inserting the energy delivery device within the skin tissue (ultrasound catheter having a handpiece 122 and a treatment shaft 124, is employed to disrupt subcutaneous structures, figs. 17A-17B), wherein inserting the energy delivery device within the skin tissue further comprises inserting in the skin tissue an interstitial device selected from the group consisting of needles, stylets, catheters, probes and microneedles (plurality of extendable elongated elements may be selected from the group consisting of needles, electrodes, and cutting elements, para. [0028]). It would have been obvious to one skilled in the art at the time of the invention to modify the method taught by Makin et al to include the interstitial device as taught by Deem et al. for the purpose of applying energy to the target tissue.

Regarding claim 33, Makin et al. disclose a method of treating a patient for a condition of hyperhidrosis (excessive activity of these glands also results in copious amounts of abnormal sweating "hyperhidrosis", primarily under autonomic neuronal control; reduction of sweating from under the armpits and other regions is a particularly desirable effect, para. [0003]), comprising identifying an area of skin tissue on a patient comprising a layer of sweat glands, wherein the area of skin tissue produces excessive sweat relating to the hyperhidrosis (system configured to deliver ultrasound energy to the regions of the superficial tissue such that the energy can be deposited at the particular depth at which the aberrant sweat gland population is located, para. [0005]), and delivering energy to the treatment zone to yield a treatment effect, said treatment effect reducing the amount of sweating from the area of skin tissue (treatment resulting from ultrasound energy delivery in the region of sweat glands used to achieve selective ablation of regions of sub-epidermal region, para. [0029]), but Makin et al. does not disclose grasping the area of skin tissue to form a skin fold comprising a first side and a second side, wherein the layer of sweat glands corresponding to the first side is adjacent to the layer of sweat glands corresponding to the second side such that the layers comprise a treatment zone. Deem et al. however, teaches a method of treating a patient by delivering energy to the skin tissue (methods and apparatus for achieving disruption of subcutaneous structures, para. [0061]), including grasping the area of skin tissue to form a skin fold comprising a first side and a second side (skin 102 is sucked up on both sides of needles 62 that are deployed out of the handpiece 268, fig. 7B), wherein the layer of sweat glands corresponding to the first side is adjacent to the layer of sweat glands corresponding to the second side such that the layers comprise a treatment zone (microneedles 62 figs. 8A-B adapted to extend through the dermal layers 104 and into the subdermal layers 106, 108, 110 , fig. 1, where treatment is desired, para. [0082]). It would have been obvious to one skilled in the art at the time of the invention to modify the method taught by Makin et al to include the skin fold as taught by Deem et al, for the purpose of directing energy to the treatment zone.

Regarding claim 34, Makin et al. further disclose applying protective cooling to at least a portion of the area of skin tissue (cooling/coupling control systems provided to remove waste heat from an exemplary probe and provide a controlled temperature at the superficial tissue interface, para. [0039]).

Regarding claim 35, Makin et al. further disclose wherein applying protective cooling to at least a portion of the area of skin tissue further comprises positioning a cooling element proximate the skin fold (cooling/coupling control systems provided to remove waste heat from an exemplary probe and provide a controlled temperature at the superficial tissue interface, para. [0039]).

Regarding claim 36, Makin et al. further disclose positioning a cooling element proximate the skin (cooling/coupling control systems provided to remove waste heat from an exemplary probe and provide a controlled temperature at the superficial tissue interface, para. [0039]), but Makin et al does not disclose positioning a first cooling element proximate the first side of the skin fold and a second cooling element proximate the second side of the skin fold. Deem et al. however, teaches a method of treating a patient by delivering energy to the target tissue (methods and apparatus for achieving disruption of subcutaneous structures, para. [0061]), including positioning a first energy delivery element proximate the first side of the skin fold and a second energy delivery element proximate the second side of the skin fold (skin 102 is sucked up on both sides of needles 62 that are deployed out of the handpiece 268, to deliver ultrasound energy, fig. 7B). Deem et al does not specifically disclose wherein the energy delivery element is the cooling element as disclosed in Makin et al. However, it would have been obvious to one skilled in the art at the time of the invention to modify the method taught by Makin et al. to include positioning a first element proximate the first side of the skin fold and a second element proximate the second side of the skin fold as taught by Deem et al. for the purpose of applying cooling energy to the target tissue.

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Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
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Previous Supplemental Page

Regarding claim 37, the modified Makin et al. disclose the invention as disclosed in claim 33, but Makin et al. does not disclose wherein grasping the area of skin tissue to form a skin fold further comprises providing suction to the area of skin tissue. Deem et al. however, teaches a method of treating a patient by delivering energy to the target tissue including grasping the tissue to form a skin fold (skin 102 is sucked up on both sides of needles 62 that are deployed out of the handpiece 268, fig. 7B), wherein grasping the area of skin tissue to form a skin fold further comprises providing suction to the area of skin tissue (suction is applied to the skin and the skin is sucked up towards the base of the handpiece, wherein the needles penetrate through at least the epidermis of the patient to be treated, para. [0081]). It would have been obvious to one skilled in the art at the time of the invention to modify the method taught by Makin et al to include the suction as taught by Deem et al. for the purpose of directing treatment energy to the target tissue.

Regarding claim 38, the modified Makin et al disclose the invention as disclosed in claim 37, but Makin et al. does not disclose wherein providing suction to the area of skin tissue further comprises maintaining suction to the area of skin tissue during the treatment. Deem et al. however, teaches a method of treating a patient by delivering energy to the target tissue including applying suction (suction is applied to the skin and the skin is sucked up towards the base of the handpiece, wherein the needles penetrate through at least the epidermis of the patient to be treated, para. [0081]), wherein providing suction to the area of skin tissue further comprises maintaining suction to the area of skin tissue during the treatment (suction is maintained ad the needles penetrate through at least the epidermis of the patient to be treated, para. [0081]). It would have been obvious to one skilled in the art at the time of the invention to modify the method taught by Makin et al. to include the suction as taught by Deem et al. for the purpose of directing treatment energy to the target tissue.

Regarding claim 39, Makin et al disclose a method of reducing sweating in a patient comprising delivering energy to the target tissue, said delivery of energy at least partially disabling or destroying the at least one sweat gland to reduce sweating from the skin tissue of the patient (ultrasound energy delivery in the region of sweat glands used to achieve selective ablation of regions of sub-epidermal region, para. [0029]), wherein the skin tissue comprises a target tissue comprising at least one sweat gland (focused or directive ultrasound energy can be used for the treatment of sweat glands In the armpit, para. [0033]), but Makin et al. does not disclose elevating a skin tissue of the patient. Deem et al. however, teaches a method of treating a patient by delivering energy to the skin tissue (methods and apparatus for achieving disruption of subcutaneous structures, para. [0061]), including elevating a skin tissue of the patient (skin 102 is sucked up on both sides of needles 62 that are deployed out of the handpiece 268, fig. 7B). It would have been obvious to one skilled in the art at the time of the invention to modify the method taught by Makin et al. to include elevating the skin as taught by Deem et al. for the purpose of bringing the skin into contact with the energy delivery device.

Regarding claim 40, Makin et al. further disclose wherein delivering energy to the target tissue further comprises positioning an energy delivery device proximate to the skin tissue of the patient (probe 204 positioned proximate to the skin 210, fig 2B).

Regarding claim 41, Makin et al. further disclose wherein positioning an energy delivery device further comprises positioning proximate to the skin tissue of the patient an energy delivery element selected from the group consisting of an electrode, antenna, ultrasound transducer, laser, light emitting diode, light bulb cryogenic probe and combinations thereof (ultrasound transducer probe configured to deliver ultrasound energy to a targeted/specified depth and zone including the sweat gland, para. [0022]).

Regarding claim 42, Makin et al. disclose the invention as disclosed in claim 27, but Makin et al. does not disclose wherein positioning an energy delivery device further comprises inserting the energy delivery device within the skin tissue. Deem et al. however, teaches a method of treating a patient by delivering energy to the target tissue (methods and apparatus for achieving disruption of subcutaneous structures, para. [0061]), wherein positioning an energy delivery device further comprises inserting the energy delivery device within the skin tissue (ultrasound catheter having a handpiece 122 and a treatment shaft 124, is employed to disrupt subcutaneous structures, figs. 17A-17B). It would have been obvious to one skilled in the art at the time of the invention to modify the method taught by Makin et al. to include inserting the energy delivery device within the skin tissue as taught by Deem et al. for the purpose of directing treatment energy to the target tissue.

Regarding claim 43, the modified Makin et al. disclose the invention as disclosed in claim 42, but Makin et al. does not disclose wherein inserting the energy delivery device within the skin tissue further comprises positioning an insertion element energy delivery element proximate to the target tissue. Deem et al. however, teaches a method of treating a patient by delivering energy to the target tissue including inserting the energy delivery device within the skin tissue (ultrasound catheter having a handpiece 122 and a treatment shaft 124, is employed to disrupt subcutaneous structures, figs. 17A-17B), wherein inserting the energy delivery device within the skin tissue further comprises positioning an insertion element energy delivery element proximate to the target tissue (ultrasound catheter having a handpiece 122 and a treatment shaft 124, figs. 17A-17B is employed to disrupt subcutaneous structures of the subdermal layers 106, 108, 110 , fig. 1). It would have been obvious to one skilled in the art at the time of the invention to modify the method taught by Makin et al to include inserting the energy delivery device proximate to the target tissue as taught by Deem et al. for the purpose of directing treatment energy to the target tissue.

Regarding claim 44, Makin et al. further disclose wherein the energy delivery element is selected from the group consisting of an electrode, antenna, ultrasound transducer, laser, light emitting diode, light bulb and combinations thereof (ultrasound transducer probe configured to deliver ultrasound energy to a targeted/specified depth and zone including the sweat gland, para. [0022]).

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Regarding claim 45, Makin et al. disclose the invention as disclosed in claim 26, but Makin et al. does not disclose wherein elevating the skin tissue further comprises applying suction to the skin tissue. Deem et al. however, teaches a method of treating a patient by delivering energy to the target tissue including elevating the skin (skin 102 is sucked up on both sides of needles 62 that are deployed out of the handpiece 268, fig. 7B), wherein elevating the skin tissue further comprises applying suction to the skin tissue (suction is applied to the skin and the skin is sucked up towards the base of the handpiece, wherein the needles penetrate through at least the epidermis of the patient to be treated, para. [0081]). It would have been obvious to one skilled in the art at the time of the invention to modify the method taught by Makin et al. to include the suction as taught by Deem et al. for the purpose of bringing the skin into contact with the energy delivery device.

Regarding claim 46, Makin et al. further disclose providing protective cooling to the skin tissue (cooling/coupling control system 306, fig. 3A).

Regarding claim 47, Makin et al. further disclose wherein providing protective cooling to the skin tissue further comprises positioning a cooling element proximate the skin tissue (cooling/coupling control systems removes heat from probe to provide a controlled temperature at the superficial tissue interface and deeper into tissue, para. [0039]).

Regarding claim 48, the modified Makin et al. disclose the invention as disclosed in claim 39, but Makin et al. does not disclose wherein delivering energy to the target tissue further comprises delivering energy to a first portion of the target tissue at a first time and delivering energy to a second portion of the target tissue at a second time. Deem et al however, teaches a method of treating a patient by delivering energy to the target tissue (methods and apparatus for achieving disruption of subcutaneous structures, para. [0061]), wherein delivering energy to the target tissue further comprises delivering energy to a first portion of the target tissue at a first time and delivering energy to a second portion of the target tissue at a second time (each peripheral ground electrode is activated in a timed sequence, para. [0093]). It would have been obvious to one skilled in the art at the time of the invention to modify the method taught by Makin et al. to include the timed delivery of energy as taught by Deem et al. for the purpose of reducing muscle stimulation while providing a constant source of energy.

Regarding claim 49, the modified Makin et al. disclose the invention as disclosed in claim 48, but Makin et al. does not disclose wherein the first time and second time are separated by a predetermined period of time. Deem et al. however, teaches a method of treating a patient by delivering energy to the target tissue (methods and apparatus for achieving disruption of subcutaneous structures, para. [0061]), including delivering energy to a first portion of the target tissue at a first time and delivering energy to a second portion of the target tissue at a second time (each peripheral ground electrode is activated in a timed sequence, para. [0093]), wherein the first time and second time are separated by a predetermined period of time (needle is withdrawn leaving the enhancing agent disposed in the subcutaneous tissue for a period of time followed by energy delivery system which then supplies energy to the tissue to be treated, para. [0123]). It would have been obvious to one skilled in the art at the time of the invention to modify the method taught by Makin et al. to include the predetermined timed delivery of energy as taught by Deem et al. for the purpose of reducing muscle stimulation while providing a constant source of energy.

Regarding claim 50, the modified Makin et al. disclose the invention as disclosed in claim 49, but Makin et al does not disclose wherein the predetermined period of time is selected from the group consisting of 1-7 days, 1-4 weeks, and 1-4 months. Deem et al. however, teaches a method of treating a patient by delivering energy to the target tissue (methods and apparatus for achieving disruption of subcutaneous structures, para. [0061]), including delivering energy to a first portion of the target tissue at a first time and delivering energy to a second portion of the target tissue at a second time (each peripheral ground electrode is activated in a timed sequence, para. [0093]), wherein the first time and second time are separated by a predetermined period of time (needle is withdrawn leaving the enhancing agent disposed in the subcutaneous tissue for a period of time followed by energy delivery system which then supplies energy to the tissue to be treated, para. [0123]). Deem et al. does not specifically disclose wherein the predetermined period of time is selected from the group consisting of 1-7 days, 1-4 weeks, and 1-4 months. However, one of ordinary skill would have been well equipped to optimize the period of time through the process of routine experimentation in order to achieve optimum treatment results at the selected treatment zone. Accordingly, it would have been obvious to one of ordinary skill to have used the claimed time period as a consequence of experimental optimization. It would have been obvious to one skilled in the art at the time of the invention to modify the method taught by Makin et al. to include the predetermined timed delivery of energy as taught by Deem et al. for the purpose of reducing muscle stimulation while providing energy.

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Claims 6-12 and 19-20 lack an inventive step under PCT Article 33(3) as being obvious over Makin et al. in view of Desai.

Regarding claim 6, Makin et al. disclose an apparatus for treating a target tissue of a patient (transducer probe and control system are configured to deliver energy to a targeted/specified depth and zone where the sweat gland population is to be treated, para. [0022]), comprising a light energy source configured for transmitting light energy to an interstitial device (source of treatment may include radio frequency (RF), intense pulsed light (IPL), laser, infrared laser, microwave, or any other suitable energy source, para. [0065]), but Makin et al does not disclose an interstitial device comprising at least one needle configured for insertion proximate to the target tissue of the patient, wherein the needle is configured for receiving the light energy transmitted by the light energy source. Desai however, teaches an apparatus for treating a target tissue of a patient (device for achieving a desired radiation pattern of the transmitted energy for optimum distribution of the energy throughout the target tissue, para. [0057]), including an interstitial device comprising at least one needle (22) configured for insertion proximate to the target tissue of the patient (body tissue treatment wherein a laser energy and/or electromagnetic radiation delivery fiberoptics or waveguide is inserted through a needle in to target tissue percutaneously, para. [0013]), wherein the needle is configured for receiving light energy transmitted by alight energy source (energy source 10 supplies any of a variety of energy types including laser energy and/or other electromagnetic energy that is transmitted to a target tissue 12 through a transmission device 15, fig. 1). It would have been obvious to one skilled in the art at the time of the invention to modify the apparatus taught by Makin et al. to include the interstitial device for receiving the light energy as taught by Desai for the purpose of applying treatment energy to the treatment site.

Regarding claim 7, the modified Makin et al. disclose the invention as disclosed in claim 6, but Makin et al. does not disclose wherein the needle comprises a chromophore configured for absorbing the light energy received from the light energy source. Desai however, teaches an apparatus for treating a target tissue of a patient (device for achieving a desired radiation pattern of the transmitted energy for optimum distribution of the energy throughout the target tissue, para. [0057]), including an interstitial device comprising at least one needle configured for insertion proximate to the target tissue of the patient (body tissue treatment wherein a laser energy and/or electromagnetic radiation delivery fiberoptics or waveguide is inserted through a needle in to target tissue percutaneously, para. [0013]), wherein the needle comprises a chromophore configured for absorbing the light energy received from the light energy source (needle is inserted into the target tissue and the appropriate volume of energy concentrating substance or photosensitizing agent/dye is injected; substances particularly useful include chromophores, para. [0081]). It would have been obvious to one skilled in the art at the time of the invention to modify the apparatus taught by Makin et al to include the chromophore configured for absorbing the light energy as taught by Desai for the purpose of delivering energy to the target tissue.

Regarding claim 8, the modified Makin et al. disclose the invention as disclosed in claim 7, but Makin et al. does not disclose wherein the chromophore generates thermal energy from the light energy absorbed from the light energy source. Desai however, teaches an apparatus for treating a target tissue of a patient (device for achieving a desired radiation pattern of the transmitted energy for optimum distribution of the energy throughout the target tissue, para. [0057]), wherein the needle comprises a chromophore configured for absorbing the light energy received from the light energy source (needle is inserted into the target tissue and the appropriate volume of energy concentrating substance or photosensitizing agent/dye is injected; substances particularly useful include chromophores, para. [0081]), further wherein the chromophore generates thermal energy from the light energy absorbed from the light energy source (transmission device is installed through the needle to the target tissue, and the required energy is applied i.e. transmitted by an energy source through the transmission device and into the target tissue, wherein the energy passes most readily into the tissue having received the energy concentrating substance, para. [0081]). It would have been obvious to one skilled in the art at the time of the invention to modify the apparatus taught by Makin et al. to include the chromophore configured for absorbing the light energy as taught by Desai, for the purpose of delivering energy to the target tissue.

Regarding claim 9, the modified Makin et al. disclose the invention as disclosed in claim 8, but Makin et al does not disclose wherein the thermal energy from the chromophore causes a treatment effect to the target tissue. Desai however, teaches an apparatus for treating a target tissue of a patient (device for achieving a desired radiation pattern of the transmitted energy for optimum distribution of the energy throughout the target tissue, para. [0057]), wherein the needle comprises a chromophore configured for absorbing the light energy received from the light energy source (needle is inserted into the target tissue and the appropriate volume of energy concentrating substance or photosensitizing agent/dye is injected; substances particularly useful include chromophores, para. [0081]), further wherein the thermal energy from the chromophore causes a treatment effect to the target tissue (energy concentrating substance can include an energy activating agent/substance characterized by the property that when exposed to a particular energy type, such as a particular laser wavelength, it will react by releasing energy or chemically reacting to cause a desired effect on the target tissue, para. [0081]).
It would have been obvious to one skilled in the art at the time of the invention to modify the apparatus taught by Makin et al. to include the chromophore configured for absorbing the light energy as taught by Desai for the purpose of causing the desired effect on the target tissue.

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Regarding claim 10, the modified Makin et al. disclose the invention as disclosed in claim 9, but Makin et al. does not disclose wherein the treatment effect to the target tissue comprises heating the target tissue. Desai however, teaches an apparatus for treating a target tissue of a patient (device for achieving a desired radiation pattern of the transmitted energy for optimum distribution of the energy throughout the target tissue, para. [0057]), wherein the needle comprises a chromophore configured for absorbing the light energy received from the light energy source (needle is inserted into the target tissue and the appropriate volume of energy concentrating substance or photosensitizing agent/dye is injected; substances particularly useful include chromophores, para. [0081]), further wherein the treatment effect to the target tissue comprises heating the target tissue (photosensitizing agents and dyes, when exposed to a particular wavelength, absorb the light energy, resulting in heat generation which heats the tissue selectivity in which the agent or dye resides, para. [0082]). It would have been obvious to one skilled in the art at the time of the invention to modify the apparatus taught by Makin et al. to include the treatment effect as taught by Desai for the purpose of causing the desired effect on the target tissue.

Regarding claim 11, the modified Makin et al. disclose the invention as disclosed in claim 9, but Makin et al. does not disclose wherein the treatment effect to the target tissue comprises at least partially ablating the target tissue. Desai however, teaches an apparatus for treating a target tissue of a patient (device for achieving a desired radiation pattern of the transmitted energy for optimum distribution of the energy throughout the target tissue, para. [0057]), wherein the needle comprises a chromophore configured for absorbing the light energy received from the light energy source (needle is inserted into the target tissue and the appropriate volume of energy concentrating substance or photosensitizing agent/dye is injected; substances particularly useful include chromophores, para. [0081]), further wherein the treatment effect to the target tissue comprises at least partially ablating the target tissue (frequency and wavelength of the laser and energy source varied, or the source replaced with one of a different frequency/wave length for achieving optimum tissue ablation, para. [0094]). It would have been obvious to one skilled in the art at the time of the invention to modify the apparatus taught by Makin et al. to include the treatment effect as taught by Desai for the purpose of causing the desired effect on the target tissue.

Regarding claim 12, Makin et al. further disclose wherein the treatment effect to the target tissue comprises at least partially disabling at least one target structure selected from the group consisting of sweat glands, hair follicles, sebaceous glands, collagen and fat (localization, delivery of ultrasound energy at a depth, distribution, timing, and energy level to achieve the desired therapeutic effect of thermal ablation to treat a sweat gland, para. [0026]).

Regarding claim 19, Makin et al disclose the invention as disclosed in claim 18, but Makin et al. does not disclose wherein delivering energy to the sweat gland further comprises heating the sweat gland. Desai however, teaches a method for treating a target tissue of a patient (device for achieving a desired radiation pattern of the transmitted energy for optimum distribution of the energy throughout the target tissue, para. [0057]), wherein delivering energy to the sweat gland further comprises heating the sweat gland (photosensitizing agents absorb the light energy, resulting in heat generation which heats the tissue selectively, para. [0082]). It would have been obvious to one skilled in the art at the time of the invention to modify the method taught by Makin et al. to include heating the sweat gland as taught by Desai for the purpose of causing the desired effect on the target tissue.

Regarding claim 20, the modified Makin et al. disclose the invention as disclosed in claim 19, but Makin et al. does not disclose wherein heating the sweat gland further comprises at least partially ablating the sweat gland. Desai however, teaches a method for treating a target tissue of a patient (device for achieving a desired radiation pattern of the transmitted energy for optimum distribution of the energy throughout the target tissue, para. [0057]), wherein heating the sweat gland further comprises at least partially ablating the sweat gland (frequency and wavelength of the laser and energy source is varied for achieving optimum tissue ablation, para. [0101]).
It would have been obvious to one skilled in the art at the time of the invention to modify the method taught by Makin et al. to include ablating the sweat gland as taught by Desai for the purpose of causing the desired effect on the target tissue.

Claim 13 lacks an inventive step under PCT Article 33(3) as being obvious over Makin et al. in view of Desai, further in view of Deem et al.
Regarding claim 13, the modified Makin et al disclose the invention as disclosed in claim 9, but neither Makin et al nor Desai discloses wherein the interstitial device further comprises a microneedle patch having an optically neutral backing. Deem et al. however, teaches wherein the interstitial device further comprises a microneedle patch having an optically neutral backing (handpiece 268 includes a pad 60 conforming to the skin surface of a patient - the pad contains a plurality of microneedles 62 extending therefrom, figs. 7A-B). It would have been obvious to one skilled in the art at the time of the invention to modify the apparatus taught by Makin et al. in light of Desai to include the microneedle patch as taught by Deem et al. for the purpose of applying treatment energy to the treatment site.

Claims 1-50 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.